

Appl. No. 10/054,113  
Atty. Docket No. 8364M  
Office Action dated: 10/10/2003  
Reply Dated: 03/01/2004  
Customer No. 27752

### REMARKS

Claims 1-12 are pending in the application, with Claims 1-12 standing presently rejected. Herein, Applicants amend Claims 4, 6, and 11-12; cancels Claims 1-3; and adds new Claims 13-23, WHEREUPON Claims 4-23 remain to be examined. No additional claims fee is believed to be due.

Claims 1-3 are cancelled *without* prejudice.

Claim 4 has been amended to improve the readability of the claim by include outline-style numbering, e.g. "(a) through (c)", and have amended "the" to "; a" where suggested by the Examiner. The readability of Claim 4 has also been improved by reordering several limitations and placing some of them within the limitations "a" and "c", respectively, so that they are proximate to the claim elements that they modify. Claim 4 has also been amended to make it clearer that the first peel bond is comprised of the adhesive means of the interior surface of the applicator substrate releasably affixing the first surface of the patch "to the interior surface of the applicator substrate". Basis lies, at least, at page 4, lines 10-13 of the Specification as originally filed.

Claims 6 and 11 have been amended to make clearer that it is the "combination" therein is the "applicator/substrate" combination. Basis lies, at least, at page 4, lines 10-13, of the Specification, as originally filed.

Claim 12 has been amended to correct grammar by inserting "and" after "therewith;".

Claims 13-15 have been added to more particularly point out and distinctly claim Applicants' invention by indicating preferred materials for the applicator substrate, patch, and release substrate, respectively. Basis lies, at least, at page 11, lines 27-29, of the Specification, as originally filed.

Claims 16-17 have been added to more particularly point out and distinctly claim Applicants' invention by indicating preferred actives which the patch may comprise. Basis lies, at least, at page 12, lines 26-31, of the Specification, as originally filed.

Claims 18-19 have been added to more particularly point out and distinctly claim Applicants' invention by indicating preferred ranges for the area of the leading edge and trailing edge, relative to the circumferential lateral edge. Basis lies, at least, at page 6, lines 22-30, of the Specification, as originally filed.

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Claims 20-21 have been added to more particularly point out and distinctly claim Applicants' invention by indicating preferred areas for the leading edge contact area and the trailing edge contact area. Basis lies, at least, at page 7, lines 9-12, of the Specification, as originally filed.

Claim 22 has been added to more particularly point out and distinctly claim Applicants' invention by indicating preferred graspable means, i.e. a "tab". Basis lies, at least, at page 3, lines 29-30, and page 5, lines 3-4, of the Specification, as originally filed.

Claim 23 has been added to more particularly point out and distinctly claim Applicants' invention by indicating a preferred method of use for the applicator device, namely where the patch comprised therein is used as part of hormone therapy. Basis lies, at least, at page 14, lines 20-21, of the Specification, as originally filed.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

#### FORMAL MATTERS

Claims 1 and 4 were objected to for using the phrasing "...an interior surface the substantially planar patch comprising..." as opposed to, e.g. "... an interior surface; a substantially planar patch comprising..." (emphasis preserved from the Office Action). Applicants have cancelled Claim 1 and amended Claim 4 herein to include outline-style numbering "(a) through (c)" and have amended "the" to "; a" as suggested. As such, Applicants submit this objection is moot as applied to Claim 1 and has been obviated as applied to Claim 4, and should properly be withdrawn.

Claim 11 was objected to for using the phrasing "combination" to describe the "applicator/substrate combination". Applicants have amended Claim 11 herein to include the phrase "applicator/substrate combination" (emphasis added), as suggested. As such, Applicants submit this objection has been obviated and should properly be withdrawn.

#### NOVELTY

Claim 1 was rejected under 35 USC §102(b) as allegedly being anticipated by US 6,124,522 [herein "Schroeder"]. Applicants have cancelled Claim 1 herein, and as such Applicants submit this rejection is now moot as applied thereto. Notably, the Examiner did not reject Claim 4 (Applicant's other independent device claim), and as such Applicant's take notice of this acknowledgement that Claim 4, and those claims depending thereon, are novel. Applicants

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further submit that new claims 13-22 are also novel, at least, by virtue of their dependence (directly or indirectly) on Claim 4.

#### NON-OBVIOUSNESS

1. Schroeder in view of Peterman

Claims 2-8 and 12 were rejected under 35 USC §103(a) as allegedly being unpatentable over Schroeder in view of US 5,533,962 [herein "Peterman"]. Applicants have cancelled Claims 2-3 herein, and as such submit that this rejection is rendered moot as applied thereto. Applicants respectfully traverse the rejection as applied to claims 4-8 and 12 for the reasons set forth herein.

A. There is no teaching or suggestion to use Peterman to modify Schroeder to arrive at Applicants' invention.

Schroeder is concerned with addressing problems hindering the ease and effectiveness of applying package-enclosed adhesive [patches] (e.g. col. 2, lines 48-63), as is Applicants' invention. However, Peterman is concerned with addressing problems associated with wear conditions, during and after the removal of the [patch] from the skin (Abstract). The skilled person would not be motivated to apply the teaching of Peterman to the teaching of Schroeder, as Peterman does not seek to solve the same or even similar problems. The Examiner contends that it would be obvious to the skilled person to substitute the patch of Schroeder with the patch of Peterman "in order to provide a non-secured edge for easier and less painful peeling of the patch from a person's skin." However, neither Schroeder nor Peterman mentions such a desired feature as being provided by their respective inventions. The removal problems that Peterman seeks to address during removal relate to a dirt ring that may build up during the patch's wear period, whose cleaning upon removal of the patch, may have deleterious effects on newly healed wounds and which may also lead to bruising caused by removal of the patch (col. 1, lines 43-57; col. 3, lines 32-37). Thus, Applicants submit that the skilled person would not combine Schroeder's and Peterman's teachings to arrive at Applicants' invention, and as such, a *prima facie* case of obviousness has not been made. Therefore, Applicants' submit that the rejection is improper and should be withdrawn.

B. The combination of Schroeder and Peterman fails to teach or suggest all the claim limitations of Applicants' invention.

Assuming *arguendo* that the skilled person would find it obvious to combine Schroeder and Peterman, the skilled person would still not find all of the claim limitations Applicants' invention therein. The Examiner contends that Schroeder, although failing to teach a non-secured

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edge, does teach an applicator substrate with an adhesive contact area 5 with a leading edge contact area and a trailing edge contact area and a patch comprising a circumferential lateral edge with leading and trailing edges, which meet Applicants' claim limitations. However, the only arguably relevant teaching that Schroeder provides describing adhesive 5 is that "[a]lthough the area of component (5) is illustrated as being relatively small with respect to the area of the article, it may be quite large" (col. 6, lines 33-35; emphasis added). From this description, i.e. "it may be quite large", the Examiner appears to find teaching of a leading (trailing) edge contact area that tacks the leading (trailing) edge to the interior surface of the applicator substrate, where the leading (trailing) edge is proximate (distal) to the graspable means of the release substrate. Applicants submit that such a finding is not sound without the benefit of impermissible hindsight vision afforded by Applicants' invention. For example, the words "it may be quite large" does not teach locating the leading (trailing) edge proximate to (distal from) the graspable means. Applicants suggest that such language merely speaks to the total area of adhesive 5, which does not teach the skilled person where and how to locate the adhesive relative to the graspable means. For the foregoing reasons, at least, Applicants' submit that the combination of Schroeder and Peterman fails to teach or suggest all the claim limitations of Applicants' invention, and as such, Applicants' submit that the rejection is improper and should be withdrawn.

Furthermore, if the skilled person were to replace the patch of Schroeder with the patch of Peterman, all the claim limitations of Applicants' invention would still not be found. Peterman teaches a peripherally-raised thin wall of non-adhesive material 4c along the periphery of the patch (col. 2, lines 7-11; Fig. 4). This peripherally raised wall, which Examiner contends teaches the non-secured edge of Applicants' invention, continues along the entire periphery (i.e. no adhesive) of the patch, not, as claimed in Applicants' invention, where the patch has a leading edge (adhesive), a trailing edge (adhesive), and a non-securing edge (no adhesive). In fact, Peterman states:

"There are numerous advantages to the novel peripheral thin-layer of the present invention but the most important of which is that such a thin-layer surprisingly inhibits the formation of the dirt ring that often surrounds the wound at the periphery of the surface where the adhesive surface contacts the skin" (col. 3, lines 32-37).

For the skilled person to modify Peterman's peripheral thin-layer so that it is interrupted by the adhesive-containing leading and trailing edges would be to modify it in a way that would permit dirt deposits to form at the areas from which the peripheral thin-layer no longer protected, thus rendering it unsatisfactory for its intended purpose. As such, Applicants submit that the rejection is improper and should be withdrawn.

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2. Schroeder in view of Peterman and Wick

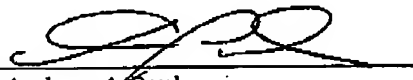
Claims 9-12 were rejected under 35 USC §103(a) as allegedly being unpatentable over Schroeder in view of Peterman and US 6,129,929 [herein "Wick"]. Applicants respectfully traverse the rejection for the reasons set forth herein.

Wick was cited for its teaching of transdermal delivery of drugs via patches, and for its teaching of placement of tabs on the applicator substrate and release substrate (Office Action at page 4), based upon Examiner's contention that Schroeder and Peterman taught the claimed invention except for these features. Applicants submit that in view of the above arguments, they have proven that a *prima facie* case of obviousness has yet to be made, and as such, Applicants submit that the rejection of Schroeder in view of Peterman and Wick must establish a *prima facie* case of obviousness of the invention including all of the limitations of Claim 4. As such, Applicants submit that Wick does not remedy the failure of Schroeder and Peterman (argued above and renewed here) to teach or suggest all of claim limitations of Applicants' invention, nor does it provide motivation to combine Schroeder and Peterman with itself to arrive at Applicants' invention, at least because Wick fails to teach a non-securing edge arrangement, or a leading edge/trailing edge/non-securing edge arrangement, alone or in combination with Schroeder or Peterman. As such, Applicants submit that the rejection is improper and should be withdrawn.

CONCLUSION

In light of the above remarks, it is requested that the Examiner enter the amendments presented, reconsider and withdraw the pending rejections, and allow the pending claims. Early and favorable action in the case is respectfully requested.

Respectfully submitted,  
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Date: 1 March 2004  
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